

IN THE UNITED STATES BANKRUPTCY COURT  
FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
	)	
W.R. GRACE & CO., <u>et al.</u> ,	)	Case No. 01-01139 (JKF)
	)	(Jointly Administered)
Debtors.	)	

**UNITED STATES' STATEMENT REGARDING ASBESTOS ANALYSIS ISSUES IN  
W.R. GRACE'S MOTION FOR SUMMARY JUDGMENT AND CLAIMANTS'  
MOTION TO EXCLUDE DR. R.J. LEE'S OPINION ON CLEAVAGE FRAGMENTS  
(DOCKET NUMBERS 4009 & 4022)**

The United States takes no position on the ultimate issue presented in the Science Trial. However, two recent Science Trial motions – W.R. Grace's Motion for Summary Judgment and Claimants' Motion To Exclude Dr. R.J. Lee's Opinions on Cleavage Fragments – present two issues related to the analysis of environmental samples for asbestos fibers that may impact the United States' claims for the recovery of costs incurred in cleaning up asbestos contamination at vermiculite processing facilities that W.R. Grace & Co.-Conn. ("Grace") owned and operated within the meaning of the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA"), 42 U.S.C. § 9607. The first issue is Grace's contention that a protocol advanced by Dr. Lee should be followed to allegedly distinguish "cleavage fragments" from asbestos fibers. The second is Grace's contention that the use of the ASTM D5755 protocol, including the "indirect preparation method" is not scientifically valid. Grace made these same arguments to the Environmental Protection Agency ("EPA") in administrative procedures related to the Libby Asbestos Site, and EPA rejected them. This Court should similarly reject Grace's arguments on these points.

### **BACKGROUND**

Grace owned and operated a vermiculite mine and associated processing facilities in and near Libby, Montana from 1963 until 1990. Amphibole asbestos is located in and near the vermiculite ore in the Libby deposit. As a result of the mining activities in Libby and the processing of Libby vermiculite at facilities in Libby and around the country, asbestos contamination spread to many other locations. In 1999 EPA began investigating asbestos contamination at numerous locations in and near Libby. EPA also began investigating asbestos contamination at vermiculite processing facilities nationwide. Soon after, EPA commenced cleanup actions at numerous locations in Libby. EPA has also begun cleanup actions at several vermiculite processing facilities nationwide, including, most notably, the Western Minerals Site in Minneapolis, Minnesota.

In 2001 the United States initiated an enforcement action against W.R. Grace pursuant to Section 107(a) of CERCLA, 42 U.S.C. § 9607(a), to recover EPA's response costs in Libby. This action, captioned United States v. W.R. Grace & Co.-Conn., et al., Civ. No. 01-72-M-DWM (D. Mont.), was litigated in the United States District Court for the District of Montana under the police powers exemption to the bankruptcy automatic stay. On December 19, 2002, the district court granted the United States' summary judgment motion on liability and rejected Grace's contentions that EPA's response actions were arbitrary and capricious. The district court found factual disputes as to the amount of costs EPA incurred and as to the recoverability of certain of those costs under CERCLA. These issues were the subject of a January 2003 trial. The district court has not yet issued trial rulings.

The United States' Proof of Claim in this bankruptcy case includes claims for cleanup costs at the Libby Asbestos Site and eleven vermiculite processing facilities nationwide. Issues regarding the appropriateness of analytical techniques used to determine the amount of asbestos in ZAI may have a bearing on the appropriateness of using the techniques to determine the amount of asbestos in environmental samples at vermiculite processing facilities. Accordingly, the United States has a significant interest in this Court's resolution of these issues in the context of the Science Trial.

### ARGUMENT

#### **I. Dr. Lee's Protocol for Excluding "Cleavage Fragments" from Asbestos Fibers Has Not Been Accepted in the Scientific Community.**

In its Motion for Summary Judgment, Grace contends that "ZAI Claimants' estimated air concentrations would be reduced at least 'ten-fold' if the non-asbestos cleavage fragments in their samples were excluded." Brief of W.R. Grace & Co. in Support of Motion for Summary Judgment at 25. Claimants cite an expert report that Dr. Richard Lee<sup>1/</sup> prepared for this proposition. *Id.* Grace's argument here is substantively identical to the argument Grace made in extensive comments it submitted on EPA's cleanup actions in Libby (again relying on a lengthy report prepared by Dr. Lee). In its comments to EPA, Grace stated:

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<sup>1/</sup> In an apparent effort to bolster Dr. Lee's credibility, Grace states: "Most recently, Dr. Lee has been asked by EPA to devise a standardized protocol for the analysis of vermiculite." Brief of W.R. Grace & Co. in Support of Motion for Summary Judgment at 8. Neither Grace's motion nor Dr. Lee's report identify a source for this contention. After due inquiry, counsel for the United States is unaware of any instance in which EPA has requested Dr. Lee to devise such a standardized protocol. On July 23, 2003, Counsel for the United States has asked counsel for Grace to provide documentary support for this claim. As of this writing, counsel for Grace has not responded.

Approximately 74 percent of EPA's analytical results include the improper counting of cleavage fragments. Cleavage fragments do not contribute to risk and are forbidden to be counted by applicable regulations. OSHA's rulemaking in 1992 evaluated whether cleavage fragments should be counted as asbestos and concluded that the evidence does not support regulating such fragments as asbestos. 57 Fed. Reg. 24310 (June 8, 1992). The applicable methods for analyzing samples also do not allow cleavage fragments to be counted.

W.R. Grace Comments on May 2, 2002 Action Memorandum Amendment and Supplemental Administrative Record No. 2, and Supplement to Comments on the Original and Supplemental Administrative Records at 3.

EPA disagreed with Grace's (and by extension Dr. Lee's) contention that EPA's contract laboratories inappropriately counted "cleavage fragments" as asbestos in its response to Grace's comments. In this document, EPA stated:

Dr. Lee's statements about the inappropriate counting of cleavage fragments do not have merit. EPA has counted asbestiform fibers and structures pursuant to the counting criteria of the methods being implemented. The counting criteria dictate discerning fibers by length, width, aspect ratio and specific physical characteristics. Following these rules, the EPA laboratories have consistently reported to EPA that the fibers found in air samples collected are populated almost exclusively with Libby amphibole fiber. . . . EPA, USGS and several other researchers (including researchers for W.R. Grace) have evaluated the nature of the mineral habit of the Libby amphibole asbestos in the Libby vermiculite. With the exception of Dr. Lee, these researchers have all concluded that the amphibole asbestos population is fibrous in nature. They all also agree that the amphibole asbestos in Libby vermiculite is quite friable, giving off airborne fibers when disturbed. Such research has been performed by Dr. Julie Yang of W.R. Grace, Greg Meeker of USGS, Arthur Langer, Drs. McDonald and Sebastien at McGill University, Dr. Amandus at NIOSH, Dr. Wake of the State of Montana, and others. . . . Dr. Lee's assertion that EPA has included a large number of cleavage fragments in its exposure estimates is without any factual foundation.

See Attachment 30 to Memorandum in Support of Claimants' Motion To Exclude Dr. R.J. Lee's Opinion on Cleavage Fragments (EPA's Response To Comments Received on the Second Supplement To the Export/Screening Plant Administrative Record) at 13. In sum, EPA's

contract laboratories identified asbestos in the Libby samples based on counting criteria of the relevant test method. Grace criticized EPA for not applying additional factors – not presented in the test method – that Dr. Lee contends indicate that most of the structures that qualify as asbestos in the test method are in fact “cleavage fragments” in the relevant method. EPA responded that the use of counting criteria that have not been adopted into the standard microscopical counting techniques is inappropriate.<sup>2/</sup> EPA also noted the general scientific consensus (including Grace’s pre-litigation assessments of the Libby ore body) that Libby amphibole is fibrous.

As part of EPA’s administrative assessment of Grace’s comments, EPA asked Mr. Gregory P. Meeker, a geologist with the United States Geological Survey and the Project Chief of both the USGS’s Denver Electron Microbeam Laboratory and its Mineral Dust and Human Health Project, to review Dr. Lee’s report.<sup>3/</sup> Mr. Meeker disagreed with Dr. Lee’s conclusion that EPA’s asbestos fiber counts improperly include cleavage fragments. Mr. Meeker stated:

Repeatedly throughout his report, Dr. Lee discusses the difference between cleavage fragments and asbestos and suggests that a substantial portion of the

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<sup>2/</sup> In its Response To Comments, EPA criticized Dr. Lee for failing to provide “concrete criteria on how he defined a cleavage fragment.” See Attachment 30 to Memorandum in Support of Claimants’ Motion To Exclude Dr. R.J. Lee’s Opinion on Cleavage Fragments (EPA’s Response To Comments Received on the Second Supplement To the Export/Screening Plant Administrative Record) at 13. In the Science Trial litigation, Dr. Lee provided Claimants with an August 31, 2001 document he authored entitled “Determination of Cleavage/Asbestiforms” which appears to set forth the unique protocol he follows to supposedly differentiate cleavage fragments from asbestos fibers. See Attachment 6 to Memorandum in Support of the Claimants’ Motion to Exclude Dr. R.J. Lee’s Opinion on Cleavage Fragments. The United States did not examine or evaluate the details of this protocol in the context of the Libby cleanup because – inexplicably – this document was not produced to the United States in the Libby litigation.

<sup>3/</sup> The United States also used Mr. Meeker’s assessment of Dr. Lee’s report as a rebuttal expert report in the Libby litigation.

particles counted by EPA (or [EPA's] contractors) were cleavage fragments rather than asbestos. Dr. Lee suggests that the distinction between cleavage fragments and asbestos particles is clear-cut and that cleavage fragments were included in the [EPA] data even though the regulations specifically forbid inclusion of these particles. I disagree with Dr. Lee's conclusions regarding EPA counting of cleavage fragments in the Libby samples for the reasons stated below.

Cleavage is a process by which minerals break along specific crystallographic planes. Amphiboles can exhibit perfect cleavage parallel to the "c" crystallographic axis and therefore can break into smaller particles, with very high aspect ratios. Amphiboles can also grow as fibers in bundles and masses. There is also a process called parting whereby long thin amphibole particles can separate from a larger amphibole particle along planes of weakness. These different processes that comminute amphiboles form a continuum with no precise boundaries or features that are easily measurable in the laboratory. From my work with the Libby amphibole, it is clear that cleavage fragments, fibers, and a complete continuum of physical forms intermediate between these two end members, that could be called partings, are present. At a microscopic level, distinguishing between these forms on single amphibole particles can be extremely difficult to impossible.

Dr. Lee cites ISO 10312 that states "The method cannot discriminate between individual fibers of the asbestos and non-asbestos analogues of the same mineral" (i.e. asbestiform particles and cleavage fragments). This statement is true, however, Dr. Lee goes on to say that ISO 10312 specifies counting of only asbestiform minerals. In fact, ISO 10312 appears to use the terms structure, fiber, and asbestos structure interchangeably (see section 9.6.1) and requires counting of all amphibole structures greater than 0.5  $\mu\text{m}$  in length with an aspect ratio of 5:1 or greater. Although cleavage fragments and asbestiform structures are defined in ISO 10312 there are no criteria or methods specified to actually distinguish between the two for the purposes of counting. The reason for this is, most likely, that it is often impossible to do this for single structures. The problem is exacerbated when there is a continuum of structures present in the sample as is the case with the Libby material. During an analysis an analyst can look for features such as splayed ends or fiber curvature to suggest that a particle is a fiber or is asbestiform. In the absence of such features the analyst must resort to the counting rules dealing with particle size and composition as outlined by the method. In other words, it is often possible to say that a particle is asbestiform but it is usually not possible to say with certainty that a given particle that meets the size criteria is not asbestiform. The policy that should be followed for structure counting is stated very clearly in OSHA Standard 1915.1001 App B "WHEN IN DOUBT COUNT," emphasis by OSHA.

Exhibit 1, Review of Expert Report of R.J. Lee, Submitted by Gregory P. Meeker, USGS

(August 30, 2002) at 1-2.

It is, therefore, wholly inappropriate for Dr. Lee to depart from the counting criteria set forth in the relevant analytical protocols in an effort to remove structures that Dr. Lee claims to be cleavage fragments. As USGS's Mr. Meeker indicates, the criteria that Dr. Lee applies (over and above the counting criteria set forth in the relevant analytical methodology) cannot demonstrate with any certainty that any given particle that meets the size criteria is not asbestiform. Needless to say, Dr. Lee's overlay criteria have not been peer reviewed or accepted by any regulatory agency. In fact, in its summary judgment brief Grace tacitly admits that Dr. Lee's approach is out of step with the scientific community. After noting that Dr. Lee has reviewed five studies<sup>4/</sup> that attempted to measure airborne asbestos generated by the disturbance of ZAI in addition to the Lees and Mlynarek study that was performed at Grace's request (and for which Dr. Lee performed the asbestos analysis), Grace states that "Dr. Lee analyzed the air data from the foregoing studies and, when the data are corrected for scientific errors (e.g., counting non-asbestiform 'cleavage fragments' in air samples as respirable asbestos fibers and using the scientifically invalid 'indirect preparation method'), Dr. Lee concluded that the air sampling results are all fairly consistent with the air data reported in the study conducted by Drs. Lees and Mlynarek." Brief of W.R. Grace & Co. in Support of Motion for Summary Judgment at 8-9 (emphasis added). The United States submits that the more relevant point is that when the Lees and Mlynarek study is corrected to eliminate the reduction in fiber count attributable to its

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<sup>4/</sup>The five cited studies are the simulation performed by the plaintiffs' experts in the Barbanti case; the simulation performed by EPA in Libby, Montana; the simulation performed by Versar, Inc. under contract with EPA; the actual demolition of a building containing ZAI in Canada by Pinchin Environmental Group; and the simulations performed by the ZAI claimants experts in the Science Trial litigation.

use of Dr. Lee's unique, non-peer reviewed protocol, its results are consistent with the results of the other five studies.

Dr. Lee's conclusion that the overwhelming number of structures in vermiculite material that other analysts (working for EPA, Claimants, and Pinchin Environmental) have identified asbestos fibers based on the dimensional criteria set forth in the various methodologies are actually cleavage fragments is inconsistent with the expert report of Dr. E.B. Ilgren that Grace attached to its summary judgment brief. Dr. Ilgren, a toxicologist, states:

A very small proportion of cleavage fragments conform to the dimensions of asbestiform fibers. Even a smaller percentage of these ever resemble a structure longer than 5  $\mu$  and less than 0.5  $\mu$  in width. . . . Cleavage fragments tend to produce 'chunks' that are, for the most part, much thicker than their asbestiform analogues. . . . Cleavage fragments cannot form appreciable quantities of extremely long, thin "pathogenic" structures. Airborne dust composed of cleavage fragments contain very few long thin structures and the majority are not biologically relevant since . . . they are too thick to be respired (ca < 2.5  $\mu$ m), too wide [to] penetrate into the deep lung (ca < 0.6 $\mu$ m), or too thick to comport with a pathogenic width (ca < 0.15 - 0.3 $\mu$ m).

Exhibit S to Brief of W.R. Grace & Co. in Support of Motion for Summary Judgment (Expert Report of Dr. E.B. Ilgren) at 8 (emphasis in original). Thus, Dr. Ilgren recognizes that the world of Dr. Lee – where long, thin "cleavage fragments" overwhelmingly predominate – simply does not exist.

Dr. Lee's difference of opinion with Dr. Ilgren regarding the prevalence of long, thin "cleavage fragments" in Libby amphibole fatally undermines Grace's reliance on Dr. Ilgren for the proposition that cleavage fragments are harmless. See Brief of W.R. Grace & Co. in Support of Motion for Summary Judgment at 24. It is certainly true that Dr. Ilgren's short, "chunky" cleavage fragments pose a significantly lower risk than asbestos fibers, which are often long and thin, if only because they are generally too thick to be respired and too wide to penetrate deep



into the lung. Dr. Ilgren's analysis does not support the conclusion that Dr. Lee's long, thin "cleavage fragments" are not toxic or carcinogenic.<sup>5/</sup> Indeed, as EPA pointed out in its response to Grace's comments on the Agency's action in Libby:

Grace grossly overstates the evidence that cleavage fragments in [and] of themselves are benign. There is considerable evidence in the literature that any difference in toxicity between cleavage fragments and fibers is explained by their native difference in morphology. That is that cleavage fragments appear to be less toxic because they tend to be shorter, thicker, and possibly less respirable than fibers. However, it is quite possible that individual, long thin cleavage fragments are as toxic as similarly sized fibers. . . .

See Attachment 30 to Memorandum in Support of Claimants' Motion To Exclude Dr. R.J. Lee's Opinion on Cleavage Fragments (EPA's Response To Comments Received on the Second Supplement To the Export/Screening Plant Administrative Record) at 13-14.

In sum, Grace and Dr. Lee contended that EPA (through its contract laboratories) included cleavage fragments in its asbestos counts related to the Libby Asbestos Site cleanup. Grace and Dr. Lee now appear to be making precisely the same argument regarding the asbestos counts in the analyses of ZAI that Claimants' experts have prepared. As reflected in the responses to this argument excerpted above, the United States believes that Dr. Lee's unique protocol for purportedly distinguishing between asbestos fibers and cleavage fragments significantly departs from accepted methodologies. Accordingly, the United States supports

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<sup>5/</sup>Grace's "cleavage fragment" argument is logically flawed as well. It is not disputed that exposure to Libby amphibole has caused significant illness to the Libby population. If R.J. Lee's contention that the large majority of this amphibole is non-fibrous cleavage fragments, one of two conclusions can be drawn: either Libby amphibole cleavage fragments are more toxic/carcinogenic than had previously been recognized or the remaining percentage of the Libby amphibole (that Dr. Lee is willing to admit is fibrous) is dramatically more potent than has previously been recognized. Neither conclusion supports a finding that Libby amphibole is more benign as a result of Dr. Lee's characterization (or re-characterization) of the structures.

Claimants' Motion To Exclude Dr. R.J. Lee's Opinion on Cleavage Fragments. Use of Dr. Lee's protocol to determine asbestos levels should not be used in the Science Trial or in any other context in this Bankruptcy Case.

**II. The Use of the "Indirect Preparation Method" Is a Scientifically Valid Technique for Preparing Surface Dust Samples of Libby Amphibole.**

Grace contends in its summary judgment brief that the analysis of surface dust samples using the ASTM D5755 protocol, which includes use of an "indirect preparation method," is not scientifically valid and that test results obtained using this protocol should be disregarded under Daubert. Brief of W.R. Grace & Co. in Support of Motion for Summary Judgment at 16-23. Specifically, Grace contends that the "indirect preparation" of the sample elevates the number of asbestos fibers that would have been found had the direct method been applied. Id. at 20. Grace also contends that the presence of asbestos in settled dust cannot be used to predict the level of airborne asbestos that may become entrained in the air as a result of disturbance of the dust. Id. at 23.

Grace similarly objected to EPA's use of the indirect preparation method for certain of its sampling efforts related to its Libby Asbestos Site cleanup, arguing in its comments to EPA's actions (again based on an expert report that Dr. Lee submitted) that "the use of indirect preparation . . . resulted in an overestimation of asbestos counts by at least an order of magnitude." W.R. Grace Comments on May 2, 2002 Action Memorandum Amendment and Supplemental Administrative Record No. 2, and Supplement to Comments on the Original and Supplemental Administrative Records at 3. EPA responded that its use of the indirect preparation method in certain situations in Libby was appropriate given the inherent friability of Libby's amphibole asbestos and the length of the fibers of concern. Specifically, EPA stated:

Dr. Lee indicates that the indirect preparation method biases the results by over-counting fibers, because the use of sonication to disperse the fibers in the liquid medium breaks up clusters that would, in the environment, remain intact. EPA disagrees with Dr. Lee's assertion and interpretation of the literature on direct vs. indirect preparation methods. Dr. Lee cites a report . . . by the Health Effects Institute which actually indicates that "direct and indirect sample preparation procedures have been shown to produce nearly equivalent results when used to measure fibers longer than 5µm in laboratory comparisons." In addition, Dr. Eric Chatfield has found that, in dusty environments such as those in Libby, the direct method may obscure airborne fibers, thus biasing the result. He suggests that the use of the indirect method in these cases may more accurately reflect exposure.

See Attachment 30 to Memorandum in Support of Claimants' Motion To Exclude Dr. R.J. Lee's Opinion on Cleavage Fragments (EPA's Response To Comments Received on the Second Supplement To the Export/Screening Plant Administrative Record) at 8. Accordingly, the United States believes that the ASTM D5755 protocol is a valid method for measuring Libby amphibole asbestos in settled dust and, more generally, that the "indirect preparation method" is a scientifically valid sample preparation technique, particularly when used to measure Libby amphibole asbestos fibers longer than 5µm.

The United States takes no position at this time on the use of the ASTM D5755 protocol and the indirect preparation method when applied to asbestos that is not friable or when used to measure fibers shorter than 5µm.<sup>9</sup> Similarly, the United States takes no position at this time on the appropriateness of using the results of settled dust analysis to quantify the amount of asbestos

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<sup>9</sup>Grace's brief places great weight on the recent Armstrong decision. See Brief of W.R. Grace & Co. in Support of Motion for Summary Judgment at 16-23. However, this decision addressed the use of the ASTM D5755 protocol and the indirect preparation methods to address asbestos in dust associated with asphalt and vinyl floor tiles, which the Court expressly found was "not considered a friable material" and that it "presents a minimal risk of asbestos release in buildings." In re Armstrong World Indus., Inc., 285 B.R. 864, 867 (Bankr. D. Del. 2002). Thus, Armstrong – even assuming it was rightly decided – does not address the use of these methodologies to quantify amount of a highly friable asbestos material – like Libby amphibole asbestos – in the sample.

that will be entrained upon disturbance of the dust.

### **CONCLUSION**

For the reasons discussed above, this Court should grant Claimants' Motion To Exclude Dr. R.J. Lee's Opinions on Cleavage Fragments. Moreover, the Court should not rely upon Dr. Lee's opinion that Libby amphibole asbestos is predominantly "cleavage fragments" or his opinion that application of the ASTM D5755 protocol and the indirect preparation method to Libby amphibole asbestos fibers longer than 5µm is inappropriate in considering W.R. Grace's Motion for Summary Judgment in the Science Trial.

Respectfully submitted,

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